

Ethical Issues of Children as Research Subjects

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About the author:

Maria Truong is a native of Wichita, Kansas. While at the School of Nursing she received the Lester T. Sunderland and the Anne Marie Buzbee Scholarships. She is a member of the Golden Key International Honour Society and achieved University of Kansas Academic Honor Roll status for eight consecutive semesters. Additionally, she was received a Clinical Excellence Award for her work in the adults clinical setting. She plans to begin her career in the Cardiovascular Intensive Care Unit at Saint Luke's Hospital of Kansas City. Her future plans include returning to school to pursue an advanced practice role as a nurse practitioner. She is thankful for the love and support of her family and friends, especially Ricky Brown and Joseph Truong. She is also appreciative to the faculty, clinical preceptors, and staff at the University Of Kansas School Of Nursing for their patience and guidance through her clinical and professional development.

Introduction

Children in past centuries were often recruited and exploited as research subjects for vaccine testing trials and to study the outcomes of infectious disease. According to Knox and Burkhardt (2007), procedures to protect children were not implemented until after World War II, and since that time, “protecting” children in research has often been interpreted as excluding children from clinical studies. Currently, only 20 to 30 percent of drugs approved by the FDA are labeled for pediatric use, and many other therapeutic interventions used for children have been derived by extrapolating data from adult studies to younger groups (Knox & Burkhardt, 2007). Continuing to apply this limited scope of evidence-based practice has the potential to cause severe, adverse effects. The need for child participation in research is indicated in order to develop new treatments and to protect against harmful practices.

Although necessary, including children in research raises serious ethical considerations. Children are considered a vulnerable population because their decision-making and comprehension skills are not fully formed. Schwenzer (2008) describes how children have a diminished ability to protect themselves, making them “more susceptible to both intentional and inadvertent harm,” and there are “legitimate concerns about their capacity to understand information presented to them and to make informed choices” (p. 1343). Although regulations and additional precautions have been implemented in order to protect this population, problems exist in the various interpretations of these guidelines, obtaining informed consent from parents and assent from the child, and recruitment strategies. The purpose of this paper is to describe current safeguards for child research, explore the continuing problems, and discuss the implications related to nursing practice and the nurse’s role in child research.

Review of the Literature

In 1998, the U.S. Department of Health and Human Services (USDHHS) added specific regulations based on risk assessment to further protect the rights and welfare of children involved in research studies.

Guido (2010) outlines how these regulations presented guidelines in child research that:

1. Does not involve greater than minimal risk.
2. Involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.
3. Involves greater than minimum risk and no prospect of direct benefit to the individual subject, but is likely to yield generalizable knowledge about the subject's disorder or condition.
4. Is not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (p. 169)

Minimal risk as defined by the USDHHS is when “probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological exam or tests” (as cited in Schwenzer, 2008, p.1344). If there is no more than minimal risk or if greater than minimal risk exists but could benefit the child, permission from one parent is sufficient. Consent from both parents is required in other categories unless a parent is deceased, incarcerated, reasonably unavailable, or only one parent has legal custody. Tait, Voepel-Lewis, and Malviya (2003) explained that children cannot legally give valid consent but they may assent or dissent to participation, although federal guidelines have not formally described regulations or

a process to do so. Assent is required and obtained “when in judgment of the Institutional Review Board (IRB) the children are capable of providing assent” (Tait et al., 2003, p. 609).

According to Chesney (2005), the interpretation of “minimal risk” and “prospect of direct benefit” may lead to confusion. The definition of minimal risk may differ between a healthy child and a child in a disease state, and there is currently no consensus on what defines minimal risk for children involved in clinical research and for children from different socioeconomic backgrounds. Application of the federal risk and benefit ratios of IRBs across the country is inconsistent, and the available data is often contradictory (Knox & Burkhardt, 2007). The subjective definition of minimal risk dictates when and what type of parental consent is needed. Therefore, obtaining standard parental consent is also variable across clinical studies. In some adolescent cases, parental consent can be waived by the IRB if there is “potential to yield great benefit to adolescents and parental permission would pose considerable risk to them” (Knox & Burkhardt, 2007, p. 314). Overall, there is no agreement and little government guidance concerning interpretation of the terms “risk” and “benefit” and risk/benefit ratios.

There is also considerable debate as to the ability of a child to assent to participation. Questions arise regarding a child’s cognitive ability to understand a described study, the risks and benefits, what it means to be a part of research, and the right to withdraw. This depends not only on age but also developmental level, health status, and environmental factors. Tait et al. (2003) conducted a study regarding child assent and concluded that children had a very limited understanding of many elements of the study they had assented to and that children 11 years of age and older had a significantly greater understanding than younger children. Meaux & Bell (2001) described studies showing that most children as young as five years were able to understand descriptions of research and were capable of giving assent, but it also revealed that

less than half of children across all age groups did not understand what it meant to stop participation or thought withdrawing was only temporary; furthermore, children “as a whole voiced willingness to participate in all hypothetical studies, yet even when children were capable of identifying ethical problems, they would continue to agree to participate” (p. 246). Overall, age parameters for obtaining child assent vary across different IRBs, while available studies contradict each other as to what age children develop appropriate cognitive abilities. Additionally, federal regulations do not describe the assent process as they do parental consent, leaving investigators at liberty to design their own process (Schwenzer, 2008).

Knox and Burkhart (2007) described how financial incentives as recruitment strategies for pediatric research have also been controversial. Poor families are more susceptible to pressure from monetary rewards, and this can create the potential for children to be coerced by their families into participating in research. Reimbursements to children and large cash payments are investigated by the IRB, but explicit standards for acceptable and unacceptable payments and other incentives for child participation in research are not clear as different agencies and organizations have conflicting rules (Chesney, 2005).

Conclusion

For several years, there has been support to close the gap in pediatric research, yet disparities continue and guidelines remain insufficient. Ethical and legal considerations should incite future revisions to provide a more concise outline of terms and guidance in applying risk and benefit ratios. More information is needed to form specific definitions on the challenges children face in daily life and during procedures. Continued research is also necessary to develop tools that accurately measure a child’s cognitive and developmental levels. Finally, regulations

should specify types and amounts of incentives and reimbursements that are appropriate to offer in exchange for research participation.

Research is at the core of evidence-based practice for nurses, and despite shortcomings and discrepancies in implementation, child research will inevitably continue due to the lack of information. There are many nursing implications to reflect on considering this reality. Pediatric nurses are often involved in recruiting children, collecting data, or assisting with protocols for research studies, even if they are not the chief investigator (Knox & Burkhardt, 2007). They must be aware of federal guidelines and ethical and legal controversies in order to advance the success of these studies while protecting the rights of child participants.

Nurses in this role should consider their responsibilities to the safety of the child as an advocate, caregiver, and health professional. They should obtain consent from the parent and obtain assent from the child separately to avoid undue coercion or influence. They should also make a concerted effort to explain procedures at a level appropriate for the child's developmental level and maturity, and afterward, the child should be asked to explain in their own words their understanding and what their involvement would mean. Nurses should also be aware of external factors that may influence child participation and take appropriate measures when these factors appear to have overtones.

As a future nursing professional currently working in pediatrics, I was surprised at how many fundamental aspects of research in this population fell short. Considering how this directly affects evidence-based practice, it made me reflect on the slow process of change in healthcare. Best practices can only be attained by advancing research efforts, and it is important for nurses to help resolve issues with child research in order to implement the best care.

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